REMARKS

The Final Office action dated March 28, 2011 is acknowledged. Claims 1-6, 8, 9 and 12-30 are pending in the instant application and according to the Final Office action, each of these claims has been rejected. By the present response, claims 1, 6 and 26 have been amended for purposes of clarification, as discussed below. Claim 1 has also been amended to recite that an aerosol is formed that comprises aerosol particles of a size below 10 μm as a mean diameter. Support for this amendment may be found throughout the specification, such as at paragraphs 13 and 16 of the specification as originally filed (paragraphs [000014] of the clean substitute specification). Reconsideration is respectfully requested in light of the amendments being made hereby and the arguments made herein. No new matter has been added.

Claim Objections

Claims 1, 6 and 26 have been objected to for various informalities. In particular, the Examiner states that claims 1, 6 and 26 should include language added to make it clear that the limitations are only occurring while the device is in use. The Examiner also states that the term "reaches" in claim 1 should be amended to "reaching." The claims have been amended accordingly. Withdrawal of the claim objection is respectfully requested.

Rejection of Claims 1-6, 8, 9 and 12-20 under 35 U.S.C. 112, second paragraph

The Examiner has rejected claims 1-6, 8, 9 and 12-20 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. In particular, the Examiner states that the term "the polymer matrix" is unclear since there is more than

one polymer matrix making it unclear as to which polymer matrix "the polymer matrix" refers. The remaining claims are rejection for depending from claim 1. Claim 1 has been amended to clarify the term "the polymer matrix," i.e., the term refers to both the polymer matrix of the first preparation and the polymer matrix of the at least one additional preparation. Withdrawal of this rejection is requested.

Rejection of Claims 1-6, 8, 9 and 12-30 under 35 U.S.C. 103(a)

Claims 1, 2, 5, 6, 8, 12, 14, 22, 23, 26 and 30 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,765,348 (Honeycutt) in view of U.S. Patent No. 5,721,257 (Baker, et al.), WO 2003/053413 (Martyn, et al.) and U.S. Publication No. 2005/0053665 (Ek, et al.). The Examiner states in the Final Office action that Honeycutt discloses a device for administration of nicotine to the human body by inhalation for the purpose of being a non-combustible simulated cigarette, wherein the device comprises a first preparation containing a free base of nicotine which is contained by absorption in a polytetrafluoroethylene element, and a second preparation containing a volatile acid, such as acetic acid, which is separated from the first preparation by an impermeable partition. The Examiner also argues that the device of Honeycutt contains a first air inlet, located to the right of section 18 (Fig. 3) directing an inhaled airstream into an oblong air supply channel around 18 (Fig. 3), a second air inlet located to the right of section 20 (Fig. 3) directing an inhaled airstream into an oblong air supply channel around 20 (Fig. 3), a common flow path where the two airstreams from the separate sections combine simultaneously due to inhalation and an outlet aperture where the common flow path leads to, all of which having a conduit cross-section. However, the Examiner acknowledges that Honeycutt lacks the first and additional preparations

comprising a polymer matrix with the agent and acid being contained in a dissolved or dispersed form. The Examiner refers to Baker, et al. for teaching a smoking cessation device with nicotine and/or additive salts including acetic acid dispersed within a PMMA polymer matrix. The Examiner thus concludes that it would have been obvious to one of ordinary skill in the art to have dispersed the nicotine and/or acid of Honeycutt in a polymer matrix as taught by Baker, et al. to safely delivery a slow release of nicotine to a user for smoking cessation.

The Examiner refers to Martyn, et al. for teaching a similar slow release composition in which therapeutic agents are dispersed in a polymer matrix and can be used in either transdermal or inhalation therapy. In this regard, the Examiner concludes that it would have been obvious to have used the dispersed form of preparations of Baker, et al. for inhalation therapy in the modified Honeycutt/Baker, et al. device since it was known that such compositions were interchangeable as taught by Martyn, et al.

The Examiner also argues that Honeycutt is silent as to the exact flow rates and nicotine release, but that Ek, et al. disclose that during inhalation therapy, depending on flow resistance, etc., an average amount of 8-10 micrograms of nicotine is released per puff from nicotine contained within cellulose matrices. Thus, the Examiner concludes that, absent a critical teaching and/or showing of unexpected results, puffs from 1-10 seconds at 0.1-1 L/min. are well known as common for smokers and that with such puffs a release of 5-250 micrograms of the nicotine would have been obvious in view of Ek, et al.

The Examiner also argues that Honeycutt is silent as to particle size and negative pressure differential but that it would have been obvious to construct the device with

appropriate size elements to create airflows and chemical balances necessary to operate the device successfully.

Regarding claim 6, the Examiner argues in the Final Office action that Honeycutt discloses that the chemical balance between volatized nicotine and acid can be controlled, but does not disclose the exact ratio of the chemical balance. However, the Examiner concludes that it would have been obvious that during inhalation a ratio of equimolar quantities of the nicotine and acid could be released in order to provide the advantage of giving the vapor a neutral pH.

Claims 3, 4, 9, 24, 25 and 27 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt, Baker, et al., Martyn, et al. and Ek, et al. as applied to claims 1, 2, 5, 6, 8, 12, 14, 22, 23, 26 and 30, and further in view of U.S. Patent No. 4,284,089 (Ray). The Examiner argues in the Final Office action that Honeycutt does not disclose the preparations containing a solvent suitable for inhalation but that Ray teaches a preparation containing water as a solvent, as well as menthol dissolved in ethanol as a flavoring. The Examiner thus concludes that it would have been obvious to provide the inhaler of Honeycutt with the solvents of Ray to provide the advantages of adjusting the humidity of vapors released and providing flavor to the vapors.

Claims 28 and 29 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt, Baker, et al., Martyn, et al. and Ek, et al. as applied to claims 1, 2, 5, 6, 8, 12, 14, 22, 23, 26 and 30, and further in view of U.S. Patent No. 5,400,808 (Turner). The Examiner argues in the Final Office action that Honeycutt discloses the device having an impermeable part and that the device can be made of any material, but does not disclose a definite composition of the whole device. The Examiner

refers to Turner for teaching a nicotine impermeable container constructed of aluminum foil coated with a copolymer of acrylonitrile and methyl acrylate. The Examiner thus concludes that it would have been obvious to provide the inhaler of Honeycutt with a material of Turner to provide the advantage of longer shelf-life of the inhaler.

Claim 13 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt, Baker, et al., Martyn, et al. and Ek, et al. as applied to claims 1, 2, 5, 6, 8, 12, 14, 22, 23, 26 and 30, and further in view of U.S. Patent No. 726,037 (Ferre). The Examiner states that Honeycutt does not disclose a peelable protective layer to form compartments containing the active agent and acid protecting them from ambient air. The Examiner refers to Ferre for teaching an inhaler with separate impermeable compartments (a, c) that have orifices (f) that can be opened or closed. Therefore, the Examiner concludes that it would have been obvious to one skilled in the art to provide the inhaler of Honeycutt with sealable compartments as taught by Ferre and for the compartments to be sealable with a peelable layer in order to provide the advantage of a longer shelf life of the contents of the compartments as well as an inexpensive disposable sealing means.

Claims 15-21 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt, Baker, et al., Martyn, et al. and Ek, et al. as applied to claims 1, 2, 5, 6, 8, 12, 14, 22, 23, 26 and 30, and further in view of U.S. Patent No. 5,660,169 (Källstrand, et al.). The Examiner argues that Honeycutt discloses the claimed invention except for a part formed by deep-drawing. The Examiner argues that Källstrand, et al. disclose an inhaler device with an upper (1) and bottom part (2) containing a compartment with a peelable seal (Figs. 3a-c) formed by deep-drawing (column 2, lines 11-14). Therefore,

the Examiner concludes that it would have been obvious to provide the inhaler of Honeycutt with deep-drawn components as taught by Källstrand, et al. in order to provide the advantage of an inexpensive way to manufacture the device.

The Applicant respectfully submits that to establish a prima facie case of obviousness, three basic criteria must be met, as set forth in M.P.E.P. § 2142. First, there must be some suggestion or motivation to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The Applicants respectfully submit that one skilled in the art would have no suggestion or motivation to combine or modify the aforementioned references in order to arrive at the present invention. Additionally, even if one skilled in the art were to consider the teachings of the cited prior art alone or in combination, each and every limitation of the present invention would not be disclosed, nor would there be a reasonable expectation of success if the aforementioned references were to be considered. Thus, withdrawal of the present rejections is believed to be appropriate.

The Applicants respectfully disagree with the Examiner's conclusion and the various obviousness rejections set forth in the Final Office action as summarized above in view of the numerous deficiencies of Honeycutt that have been established in previous Office action responses. Honeycutt simply fails to teach each and every limitation of the presently claimed invention in addition to the deficiencies acknowledged by the Examiner. As previously noted, the presently claimed invention and the disclosure of Honeycutt differ in at least the additional following aspects:

- the arrangement of the nicotine base in dissolved or dispersed form within a

polymer matrix selected from the group consisting of polyethylenes, polypropylenes, silicone polymers (polydimethylsiloxanes) and poly(meth)acrylates;

- the arrangement of the acid being dissolved or dispersed in a polymer matrix selected from the group consisting of polyethylenes, polypropylenes, silicone polymers (polydimethylsiloxanes) and poly(meth)acrylates;
- the release rate of nicotine base from the inhaler device; and
- the duration and speed of the inspiration process.

As noted above, Honeycutt does not at all teach each and every limitation of the presently claimed invention. Moreover, Honeycutt also fails to teach the limitation of for forming an aerosol comprising aerosol particles of a size below 10μm as a mean diameter as set forth in amended claim 1.

As stated in the Final Office, the Examiner concedes that the subject matter of Honeycutt is being modified in how the compositions are being stored or released (page 2, third paragraph of the Final Office action). However, it is respectfully submitted that the modifications that were conceived by the Applicants in order to store the active ingredients in a polymer matrix that additionally releases the active ingredient in an efficient amount simply cannot be considered obvious based on the cited prior art.

First, it is respectfully submitted that, contrary to the Examiner's position in the Final Office action, storing nicotine and/or basic active ingredients and volatile acids for slow release from an inhaler is not well-known in the prior art. In particular, it is pointed out that the Baker, et al. reference discloses a transdermal delivery system comprising nicotine and/or additive salts including acetic acid (col. 7, lines 20-25) dispersed in a

polymethyl methacrylate (col. 10, first paragraph). However, Baker, et al. fail to teach or suggest using these polymer matrixes for slow release of nicotine in an inhaler device.

Moreover, it would not be obvious to one skilled in the art to use the composition of Baker, et al. in an inhaler device when taking into account the reference of Martyn, et al. Martyn, et al. disclose a polymer matrix that has a totally different composition. In particular, the composition according to Martyn, et al. requires the presence of hyaluronic acid and a second biodegradable polymer (claim 1). These biodegradable polymers comprise, *inter alia*, carboxymethyl cellulose and other types of cellulose derivatives. However, the Martyn, et al. reference is entirely silent about using acrylic polymers such as polymethyl methacrylate. As the polymer matrix according to Martyn, et al. shows a totally different composition, one skilled in the art would not consider using the polymer matrix according to Baker, et al. as a storage means for the slow release of nicotine and/or other basic active agents in an inhaler device. In other words, it was not obvious to those skilled in the art that the compositions of Baker, et al. are interchangeable with respective to use in either transdermal or inhalation therapy.

Moreover, it is also submitted that the polymer matrix according to the presently claimed invention was not a composition for the release of nicotine and/or other basic active agents that was well-known for use in inhalation therapy.

The Examiner, as stated in the Final Office action, is also of the opinion that the release rate of the nicotine base from the inhaler device and the duration and speed of the inspiration process merely relate to modification of dimensions that do not patentably distinguish the presently claimed invention over the prior art. The Applicants respectfully disagree. The noted features, i.e., the release rate of nicotine base from the

inhaler device and the duration and speed of the inspiration process, do not relate to modifications that are a mere design matter. The choice of a specific release rate and duration and speed of the inspiration process in combination leads to an unexpected and superior result in view of the cited prior art. Depending on the release rate of nicotine base from the inhaler device and the velocity of the flow rate of aerosol particles of a size less than 10 μm can be formed. The formation of these aerosol particles is particularly advantageous for efficient alveolar absorption. Efficient alveolar absorption in turn is related to an efficient smoking sensation therapy without the occurrence of undesired side-effects (e.g., paragraph 16 of the description as originally filed).

It is submitted that the choice of a specific release rate of nicotine base and duration and speed of the inspiration process was not obvious in view of the cited prior art teachings, and in particular further in view of Ek, et al. Ek, et al. fail to make up for the deficiencies of the other cited prior art and merely disclose that it is possible to release 8 to 10 μg nicotine per puff from a nicotine inhaler device (paragraph 106). However, the Ek, et al. reference is entirely silent about any means to achieve the release of this amount from an inhaler device. In particular, there is nothing in Ek, et al. that discloses a specific velocity of inspiration that is required to obtain the efficient amount of nicotine base. Moreover, the Ek, et al. reference neither suggests nor even hints at an optimum velocity to prepare aerosol particles that allow for efficient therapy of smoking sensation because of superior alveolar absorption.

Furthermore, it is submitted that the reference of Ek, et al. cannot be regarded as an enabling reference for the presently claimed invention since it pertains to an inhaler device that is arranged fundamentally differently from that of the presently claimed

invention. For example, the nicotine base is stored in cellulose. The Ek, et al. reference is also entirely silent about the presence of a second preparation comprising a volatile acid and the presence of a first inlet aperture and a second air inlet aperture. Thus, as there are no teachings in Ek, et al. that disclose how to modify the inhaler device according to Honeycutt, et al. or otherwise make up for the deficiencies of Honeycutt, one skilled in the art would not arrive at the presently claimed invention by combining the teachings of Honeycutt and Ek, et al., or even with the teachings of Baker, et al. and Martyn, et al.

The further cited references fail to make up for any of the numerous deficiencies of Honeycutt, Baker, et al. and Ek, et al.

It is therefore respectfully submitted that the present invention defined in the presently amended claims is patentably distinguishable over the prior art teachings under 35 U.S.C. 103(a). Based on the aforementioned differences, each and every element of the present invention recited in the present claims is not set forth in Honeycutt alone or in combination with the secondary references, nor would one skilled in the art be motivated to modify Honeycutt to arrive at the presently claimed invention. Therefore, the Applicant respectfully requests that this rejection be withdrawn.

Conclusion

For the foregoing reasons, it is believed that the present application, as amended, is in condition for allowance, and such action is earnestly solicited. Based on the foregoing arguments, amendments to the claims and deficiencies of the prior art references, the Applicant strongly urges that the obviousness-type rejection and anticipation rejection be withdrawn. The Examiner is invited to call the undersigned if

there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

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